UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8
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Ref: 8EPR-SR

July 30, 2001

Ms. Barbara O'Grady
Colorado Department of Public Health
and the Environment
4300 Cherry Creek Drive South
Denver, CO 80246-1530

RE: Vasquez Boulevard/ Interstate 70 (VB/I-70)Site

Dear Barbara:

Enclosed please find EPA's responses to comments provided by the Colorado Department of Public Health and Environment on the July, 2000 draft Baseline Human Health Risk Assessment for the VB/I-70 Site. EPA revised the draft document as described in these responses. In addition, as a result of your agency's review of the revised document, a number of additional issues were identified. EPA will ensure that the final Baseline Human Health Risk Assessment incorporates the following additional modifications in order to resolve these issues:

1. The assessment of risks associated with ingestion of garden vegetables will clarify that the unexpectedly high value of arsenic in one vegetable sample might be attributable to incomplete removal of soil from the sample or may be due to uptake into the surficial layers of the plant. The unexpected result may not be a true outlier. Additional language will be added to Section 4.4.3 and Section 2.6.3.

2. EPA will provide a more complete rationale for using the 90th percentile arsenic soil concentration in each individual yard as the exposure point concentration for the subchronic exposure scenario.

3. EPA will include a discussion about the uncertainties associated with applying the site specific relative bioavailability adjustment to the dose associated with exposure to dust. The discussion is appropriate in Section 4.5, Uncertainties in the Arsenic Risk Assessment.

4. EPA will add language to Section 4.5 to explain the limitations of the available urinary arsenic data in evaluating whether soil pica behavior may be resulting in acute arsenic exposure.

5. EPA will provide the rationale for why available blood lead data from people who reside in the VB/I70 site are not sufficient to support a site specific adjustment of the geometric standard deviation of blood lead levels or GSD. EPA will also add language to

the description of the Denver Lead Survey to clarify that a younger age group was targeted for this study.

6. EPA will add language which indicates that comparisons of the results of blood lead levels measured during study 2 and study 3B suggest blood lead levels within VBI70 are generally similar to but may be somewhat higher than values seen in the national survey although these levels are not atypical for the risk factors present in the population tested.

7. EPA agrees that the discussion of the Three Cities Study is more appropriate in the Feasibility Study and will remove it from the final Baseline Human Health Risk Assessment.

8. EPA will clarify (by adding language and possibly rearranging text) that the purpose of the alternative IEUBK model runs is to illustrate that the IEUBK model's sensitivity to the value of the GSD parameter. References to other sites will be removed. In addition, another alternative model run will be performed which uses a lower GSD and new estimates of the dietary lead intake values.

Thank you for your input into this important document. If I can answer any further questions you may have, please call me at (303) 312-6579.

Sincerely,

Bonnie Lavelle
Remedial Project Manager

enclosure

cc (w/encl): Jane Mitchell

EPA RESPONSES TO
COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
COMMENTS ON THE DRAFT VBI70 BASELINE RISK ASSESSMENT

General Comments:

Discussions in the risk assessment of arsenic risk levels should include information about background levels of risk associated with concentrations of arsenic in soil that would be typical of an uncontaminated neighborhood. This information is particularly important to provide some perspective when presenting the percent of homes exceeding a 1E-05 risk for different communities in the study area (for example, see Table ES-2) and when presenting cancer risk maps (see Figure 4-1).

Response: The revised document now includes an estimate of the range of arsenic concentrations that is likely to be typical of background and the predicted cancer risks associated with average background levels (see Section 4.4.2). The document has been modified to also present this information in the executive summary and in the risk characterization section.

Sub-acute exposure to arsenic has been assessed based on direct use of a LOAEL (LOAEL = 0.05 mg/kg-day based on studies referenced on page 36 of the risk assessment) as the sub-acute oral reference dose. No uncertainty factors have been applied to adjust the LOAEL to account for possible differences in toxicity to sensitive populations or for general weakness in the database available. This is contrary to standard EPA methodology recommended for derivation of chronic or acute reference toxicity values. The toxicity value adopted should include consideration of standard uncertainty factors.

Response: In response to these comments regarding the toxicity factor used in EPA's evaluation of short term exposures, EPA revised the evaluation of non-cancer risks from short term exposures. The final baseline human health risk assessment presents the revised evaluation. Conceptually, short term exposures of potential concern could include a range of alternative scenarios considering differences in frequency, duration, and exposure area. The short term scenario most likely to yield the highest risk is the acute exposure to a child with soil pica behavior. EPA developed two scenarios of soil pica exposures in order to illustrate the range of uncertainty in the toxicity factors and the exposure parameters. Case 1 uses the ATSDR provisional MRL as the reference dose. The provisional MRL, 0.005 mg/kg/day, is based on the 0.05 mg/kg/day LOAEL divided by a safety factor of 10. Case 2 uses the a toxicity value of 0.015 mg/kg/day based on a NOAEL. This value has not undergone formal Agency review or approval

and is considered draft but was recommended for use at VB/I70 by the Regional Toxicologist. Supporting documentation for the Case 2 toxicity value is included as an appendix to the final document.

The exposure frequency chosen to assess the potential for sub-acute risk is ½ (i.e., assumes a child may be exposed 1 out of 2 days – see page 35 of the risk assessment). As discussed previously by the working group, the soil intake rate and exposure frequency assumptions for these shorter-term exposures are highly uncertain. If, as stated on page 36 of the risk assessment, the data do not support quantitative assessment of a one day (acute) event, ("... No reliable estimate of an acute (single dose) RfD is available..."), it seems unlikely that the data are sufficient to quantify a two-day exposure. It would be preferable to minimize the uncertainty in the shorter-term risk estimates by matching the exposure frequency assumed in the risk assessment to the actual time period of exposure in the study selected as the basis of the sub-acute RfD.

Response: EPA has re-evaluated the entire approach used for assessing acute exposures (one dose) and sub-acute exposures (repeated exposures over a short time scale), taking these comments into consideration. The final baseline human health risk assessment presents the revised assessment. Conceptually, short term exposures of potential concern could include a range of alternative scenarios considering differences in frequency, duration, and exposure area. The short term scenario most likely to yield the highest risk is the acute exposure to a child with soil pica behavior. The acute pica scenario developed in the final document focuses on the risks from a single event in which a child ingests a large mass of soil from a small location within a yard.

The RBA derived from the swine study is based on site soils from five locations within the VB-I70 study area. While these data do probably provide a more precise estimate of absorption of arsenic from site soils than do studies based on exposure to arsenic in drinking water, it is not necessarily the case that this information should be extrapolated to absorption of dust. Potential chemical and physical differences between soil and dust, such as solubility and particle size, which may affect absorption rates and resuspension rates, have not been characterized. Applying the RBA to dust as well as soil is a very broad extrapolation of the swine study data which is highly uncertain. The RBA-adjusted reference dose value should be applied to the soil dose estimate only and not to the dust exposure dose. Also, see specific comment #11 regarding the application of the RBA results derived from the swine study.

Response: While EPA agrees that dust is not identical to soil, there is an explicit assumption that arsenic in dust is derived by contamination of the dust with fine particles of yard soil carried into the house by air or on clothing, shoes, pets, etc. Since the RBA is based on measurements of yard soil samples that were sieved to isolate the fines, EPA believes that it is better to assume the RBA in dust is the same as in soil rather than assuming a default value based on arsenic in water.

these and other comments into consideration.

4.Page ES-14, *Conclusions* - The last sentence of this section ("...The pattern of properties with lead contamination does not appear to be closely linked to those that are impacted by arsenic.") should be modified. To be consistent with conclusions on pages ES-5, ES-14 (second full paragraph), and page 6, the conclusion should indicate that (a) there is only a weak correlation between the occurrence of elevated arsenic and lead concentrations in soil, which indicates that the source of these two chemicals is not likely to be the same, but that (b) there is a similar spatial distribution seen for both lead and arsenic at individual impacted properties, with an apparent boundary effect between the impacted property and the adjacent property.

Response: The text has been modified as recommended.

5.Table ES-1 – For clarity, it would be helpful to add a footnote to indicate that the Globeville data (N=22) summarized in this table was collected from areas south of I-70 and west of I-25, if that is the case.

Response: The location of data from the Globeville neighborhood will be clarified.

6.Tables ES-2, ES-3, and ES-4 – These tables need to include footnotes describing the terms used in the various column headings (such as CTE, RME, P10).

Response: The tables have been modified to minimize the use of acronyms and to define acronyms where they are used.

7.Page 7, section 2.3.3, *Biomonitoring* – As discussed in previous comments submitted on arsenic biomonitoring issues, CDPHE does not agree that the reference value for arsenic in hair shown in the table at the bottom of this page is representative of typical values in an unexposed U.S. population.

Response: The risk assessment will be modified to include a more appropriate estimate of the reference value for arsenic in hair.

8.Page 14, section 2.6.2, *Residential Dust Sampling*, 2nd paragraph – Please add that individuals living in the two homes with high dust lead concentrations were contacted by a health care worker to discuss the possible source of lead dust in their home and that families were offered blood lead testing.

Response: The text has been modified as recommended.

9.Page 16, 1st full paragraph – Soils data for school S12 are discussed in this section of the text, but the data are not included in the summary in Table 2-5.

Response: The code for the school is S8. The text has been corrected.

10.Page 19, section 3.2.2, *Workplace Exposures* - Appendix C provides a reasonable screening approach for assessing worker exposure, however it is not typical to use an average exposure point concentration for such a screening calculation. Rather, a maximum soil concentration would typically be used for screening purposes. Also, the rationale for not assessing this potential exposure pathway due to results of soil sampling at commercial/industrial properties in the vicinity of the Globe plant is questionable, given the uncertainty of a common source of arsenic for these two areas.

Response: The calculations presented in Appendix C are used to establish risk-based concentration (RBC) values for workers, and are not based on any measured values (average or maximum) at the site. A comparison of the RBC values to both average and maximum values from the Globe site is presented in Section 3.2.2. As seen, the mean values are far below the RBCs, and even the maximum average across a property is lower than the RBC for both arsenic and lead, supporting the view that neither chemical is of concern. While it is true that the data are from the area around Globe rather than the VBI70 site itself, if there were any bias in the data, it is likely that commercial properties near Globe are more likely, not less likely, to be impacted by smelter releases since the Globe smelter operated for many more years than the Omaha Grant or Argo smelters. Also, consider that a comparison of the summary statistics for the Asarco Globe site data and the VB/I70 Phase III data indicate that the mean and maximum arsenic concentrations for the Asarco Globe data set (48 ppm and 3873 ppm respectively) are higher than the Phase III data set (34 ppm and 759 ppm respectively), indicating that, in general, the Globe study area is more highly impacted by arsenic than the VB/I70 study area.

Nevertheless, because of CDPHE's concern, EPA will consider developing a sampling ad analysis program during remedial design with the objective of reducing the uncertainty in the knowledge of arsenic and lead levels in commercial properties in the VB/I70 site.

11.Page 30, section 4.3.2 , *Toxicity Summary for Arsenic – Beneficial Effects*, 2nd paragraph, 1st sentence – The conclusion in the second paragraph ("If arsenic is beneficial or essential in animals, it is also likely to be so for humans") seems speculative, given the observed differences in arsenic toxicity for animals versus humans and the lack of testing for essentiality in humans. This sentence should be deleted.

Response: EPA does not agree. Please note that the text makes it clear that this is a speculation. Because toxicokinetic differences exist between animals and humans with regard to arsenic is not sufficient reason to discount the notion that if arsenic is beneficial in one species of mammal it is also likely to be beneficial in other species of mammal.

12.Page 31 Section 4.3.3. *Adjustments for Relative Bioavailability*. – Because fairly large (2 to 3-fold) unexplained differences were seen in RBA values for the 5 different test materials used in the swine study, use of a single site-wide average RBA is questionable. EPA should consider applying an area-specific RBA or using the 95%UCL of the maximum RBA value of 0.43 (from test material 2).

Response: EPA does not agree. First, some of the apparent variation is attributable to an error in the calculation of the RBA for Test Material 4. After correction, the inter-sample range is reduced. Second, the form of arsenic appears to be the same (arsenic trioxide) at all locations, so there is no reason to expect that there should be significant variations between locations. Third, the in vivo bioassay of RBA is not highly precise, and random variations in measured values around a true site-wide value are expected. EPA believes that using the 95% UCL based on all samples is more than adequate to account for the uncertainty and variability in the data.

13.Page 35 – See general comment # 3 regarding exposure frequency (EF) assumptions.

Response: EPA has re-assessed the entire approach used for assessing acute exposures (one dose) and sub-acute exposures (repeated exposures over a short time scale), taking these and other comments into consideration.

14.Page 36 – See general comment 2, regarding use of a LOAEL value for a sub-acute RfD.

Response: EPA has re-assessed the entire approach used for assessing acute exposures (one dose) and sub-acute exposures (repeated exposures over a short time scale), taking these and other comments into consideration.